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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,867	12/07/2001	Serge Beaudoin	004208.00034	9077

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

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DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/004,867

Applicant(s)

BEAUDOIN ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17 (in part), drawn to compounds and composition of formula (I) wherein A, B, and D are all substituted carbon atoms, and R² is pyridyl, classified in class 546, subclasses 304, and 314.
 - II. Claims 1-17 (in part), drawn to compounds and composition of formula (I) wherein A, B, and D are all substituted carbon atoms, and R² is alkyl, carbocycloalkyl, aryl, or (aryl)alkyl, classified in class 564, subclass 80+.
 - III. Claims 1-17 (in part), drawn to compounds and composition of formula (I) wherein one of A, B, and D is a N atom, or N-O, classified in class 546, subclass 112.
 - IV. Claims 1-17 (in part), drawn to compounds, and composition of formula (I) wherein A and B are N atoms (one of them optionally is N-O), and D is a substituted carbon atom, classified in class 544, subclass 253.
 - V. Claims 1-17 (in part), drawn to compounds, and composition of formula (I) wherein B and D are N atoms (one of them optionally is N-O), and A is a substituted carbon atom, classified in class 544, subclass 235.
 - VI. Claims 1-17 (in part), drawn to compounds, and composition of formula (I) wherein A and D are N atoms (one of them optionally is N-O), and B is a substituted carbon atom, classified in class 544, subclass 349.

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VII. Claims 1-17 (in part), drawn to the remaining compounds, and composition of formula (I) that are not mentioned in the above groups, classified in classes 544, 546, 548, 549, various subclasses. Further restriction and election of species will be required if this group is elected.

VIII. Claims 18-22, drawn to various methods of treatment, classified in class 514, subclasses 230, 249, 258.1, 278, 299, 352, 357, 601, 602, 605. Further restriction and election of species will be required if this group is elected.

The inventions of groups I-VII differ from each other because each group is drawn to a ring system that is distinct and patentable over each other. Essentially, these are seven independent inventions as compounds of one group can be utilized alone, and not in combination of those in other groups. Note, with a variable core as such, the common property is not enough to keep seven groups in the same Markush claim. Furthermore, a prior art that renders obvious one invention would not do so to the others. Thus, restriction for examination purpose as indicated is proper. However, should applicant traverse on the ground that the seven groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the seven groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the invention unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Inventions Groups I-VII and VIII are related as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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method for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different method of using that product (MPEP § 806.05(h)). In the instant case the various methods of use can be practiced with other commercially available drugs.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for other groups, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Mr. Joseph Skerpon on 5-12-03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17 (in part). Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

4. Claims 16 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a dependent claim cannot refer to another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 16 and 17 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. In claim 1, the limitation of “prodrug” is indefinite because the definition in the specification does not identify a specific ester or amide moiety, nor does it specify a location for such a moiety. Thus the final structure of such a “prodrug” is indeterminate.
- b. In claim 1, it is not clear whether R² can be substituted.
- c. Claims 2 and 8 lack antecedent basis because they recite R² as being a substituted pyridyl ring. However, claims 1 and 7 do not indicate if such a ring can be substituted.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Scope of Enablement:** Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation and use of compounds of formulae (I) and (III), does not reasonably provide enablement for the preparation and use of their 'prodrugs'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

On page 31, the specification provides a definition for a "prodrug". However, said definition is vague as to what constitutes an ester, amide or a terminal peptide. Furthermore, it does not specify the location of such an ester, amide or a terminal peptide. By referring to the

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reference of Bungaard alone, it does not sufficiently enable one skilled in the art to select a particular ester, amide or terminal peptide, and its location on the ring or on the side chain. Often time, a “prodrug” has active metabolites, which can contribute to the biological activity or adverse effect. Thus, the scope of a “prodrug” would require undue experimentation not only for preparation, but also for a pharmacokinetic profile. Also, as has been ruled by the court in *Genetech Inc. v. Novo Nordisk*, relying on the knowledge of one skilled in the art cannot cure such a deficiency in enablement (**Genetech Inc. v. Novo Nordisk**, 108 F.3d 1361, 42 USPQ 2d 1001 (Fed. Cir. 1997)).

7. **Enablement:** Claims 1-3, 5, 7-9, 11, and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. When R⁵ and R⁶ forming a ring, the claimed formula (I) becomes a substituted **spiro-tricycle**. The specification does not provide a generic teaching of how such a spirocycle can be formed. Besides, none of the working examples details how a spiro-tricycle can be made. Thus with an unpredictable nature of the chemical art, one skilled in the art will have to carry out undue experimentation to make a spiro-tricyclic compound, and test it for biological activity.

Information Disclosure Statement

The IDS of 08-06th-02 has been considered. The cited references do not read on the instant elected group.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Tamthom N. Truong
Examiner
Art Unit 1624

May 27, 2003